

## **REMARKS/ARGUMENTS**

The following remarks are submitted in response to the Final Office Action dated December 18, 2008.

Claims 1-9 have been previously canceled without prejudice as to resubmission. Claim 14 is amended herein to correct a typographical error and provide proper antecedent basis. Entry of the present amendments is requested to place the application in better form for appeal and/or in condition for allowance. Upon entry of this amendment, claims 10-21 will be pending in the present application. No new matter has been added.

Reconsideration and allowance are respectfully requested in view of the following remarks.

### ***1. The Prior Art Rejection***

#### **i. 35 U.S.C. §102(e) Rejection - Cherif-Cheikh**

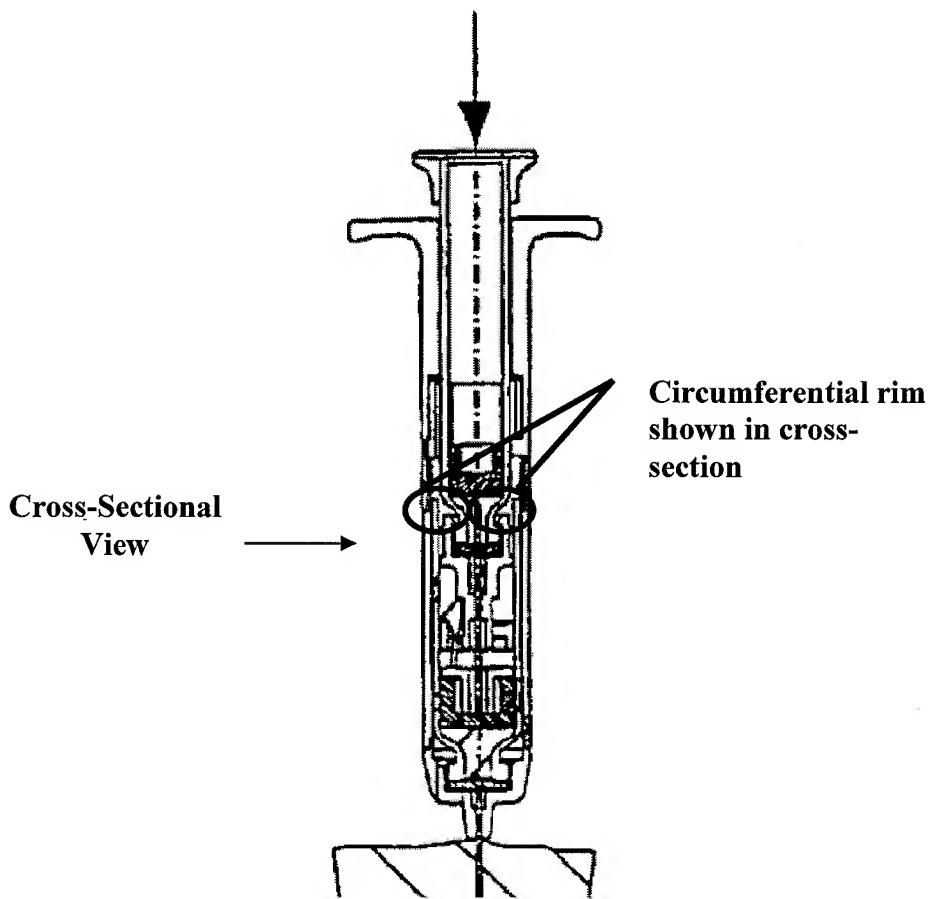
Claims 10-13 and 21 have been rejected pursuant to 35 U.S.C. §102(e) as being anticipated by U.S. Patent No. 6,902,543 (hereinafter “Cherif-Cheikh”).

Cherif-Cheikh discloses a syringe device for reconstituting a solution, suspension or dispersion. The syringe device includes a container 11 which stores a solvent, a transfer needle 18 and a second container 13 for storing a lyophilizate (See col. 7, lines 64-67; col. 8, lines 1-11). Cherif-Cheikh, however, does not appear to disclose all the required limitations of independent claims 10 and 21. Namely, Cherif-Cheikh fails to disclose at least:

- (1) “at least two protrusions being formed on an inner side of the bracket, said protrusions being in contact with the bottom opening of the solvent bottle”;
- (2) “at least two protrusions are formed on an inner side of the bracket, the protrusions being in contact with the bottom opening of the solute bottle”; and
- (3) “a guiding recess being provided at a central portion of the first sealing plug”

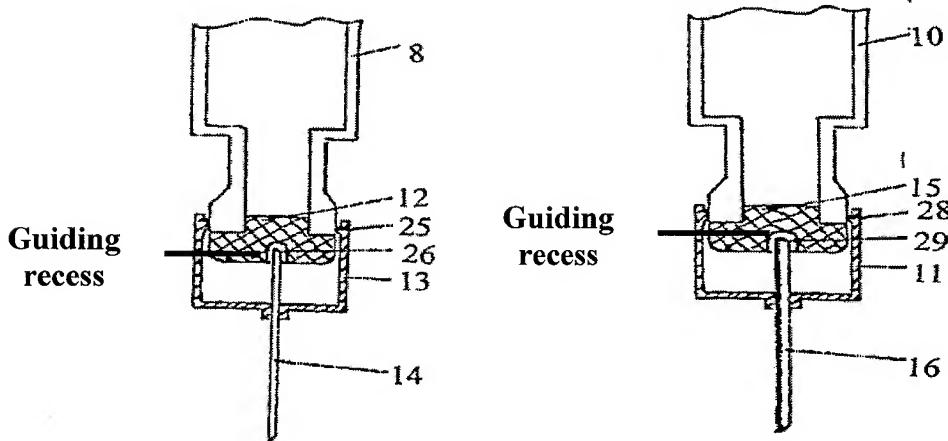
For purposes of clarification, the aforementioned limitations, i.e. protrusions, guiding recess and their position relative to the other claimed elements are structural limitations and not merely functional limitations of claims 10 and 21 as previously suggested by the Examiner.

Cherif-Cheikh fails to disclose at least two protrusions located on an inner surface of the brackets in contact with the bottom opening of the solute bottle and solvent bottle, as required by independent claims 10 and 21. Notably, Cherif-Cheikh fails to mention and none of the figures show at least two protrusions positioned on the brackets for receiving the sealing caps 22 and 28. Because all the figures of Cherif-Cheikh are presented as cross-sectional diagrams, at the most, the figures only suggest that the bracket may have a single circumferential lip or rim, as shown below. Cherif-Cheikh does not expressly disclose, teach or suggest a bracket having at least two protrusions. Therefore it fails to disclose all the elements required by independent claims 10 and 21.



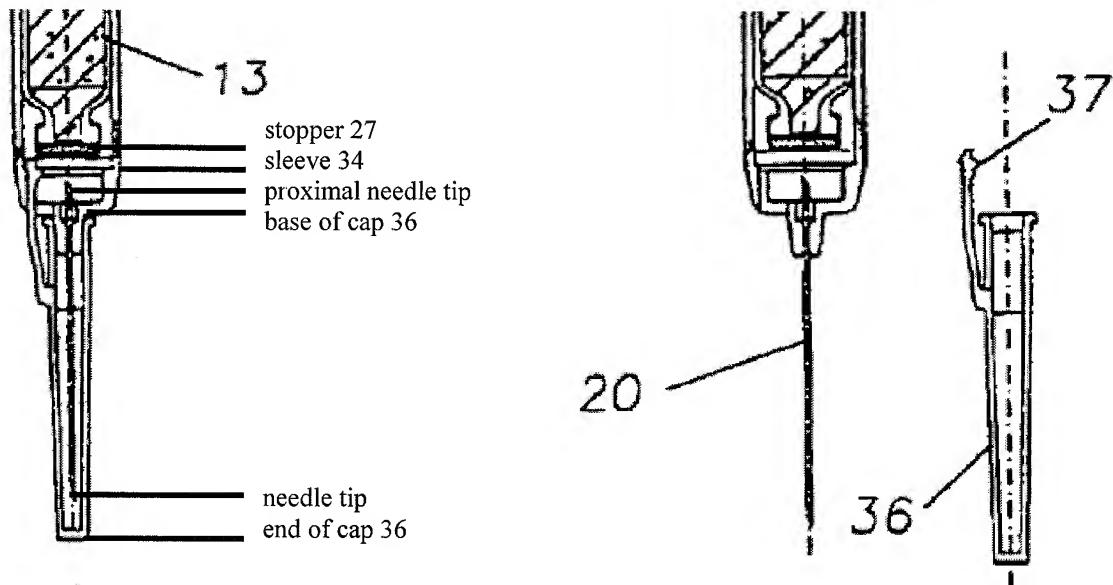
Applicant also wishes to preemptively assert that the claimed protrusions are not obvious features. In the present application, protrusions 25 and 28 may be a plurality of fins, hooks or nipples (See page 8, line 29; page 9, line 28; page 10, line 1) which function to retain the solute and solvent bottles in their respective brackets. Furthermore, the protrusions prevent the solvent and solute bottle from being removed from the syringe and subsequently reused. Therefore, the protrusions help to ensure that the syringe is only used once and is subsequently discarded to avoid any risk of contamination that results from reuse of the solvent bottle, solute bottle or syringe (See page 9, lines 20-23). By contrast, Cherif-Cheikh is structured to enable removal and replacement of solvent container 11 (See col. 10, lines 50-56).

Cherif-Cheikh also fails to disclose “a guiding recess being provided at a central portion of the first sealing plug” of the solvent bottle as required by claims 10 and 21. The guiding recess 26, 29 of the present application is illustrated in Figs. 6-7 of the present application below. At most, Cherif-Cheikh teaches that sealing cap 22 of the solvent bottle may have a pierced center (See col. 8, lines 19-23). No where in the specification or in the figures, however, does Cherif-Cheikh disclose a guiding recess positioned in its sealing disk membrane 21 of the solvent bottle.



Furthermore with respect to claim 10, Cherif-Cheikh also fails to disclose a projecting jacket which covers the second sealing plug, bracket and syringe needle. For purposes of clarification, the projecting jacket and its position relative to the other claimed elements are structural limitations and not merely functional limitations of claim 10 as previously suggested

by the Examiner. In describing Figure 1, Cherif-Cheikh discloses a cap 36 attached to a distal end of base 35 (See col. 10, lines 30-31; Figures 1, 9). Cap 36 is never disclosed or shown as extending past a distal end of base 35. Nor is it ever shown as covering stopper 27 (i.e. the sealing plug), a proximal end of the syringe needle 20, or sleeve 34 (i.e. the bracket). Cap 36 is only shown as covering a portion of the needle body and a distal tip of the needle. A lock 37 constructed as an arm extending from cap 36 and held by the head of cartridge 13, prevents the withdrawal of cartridge 13 (See Figure 1; col. 14, lines 37-38). Because lock 37 is constructed as a thin arm member offering no housing or protection, it does not cover sleeve 34, stopper 27 or a proximal end of the needle; furthermore, as shown below, lock 37 does not even extend over any portion of stopper 27.



Cherif-Cheikh also fails to disclose all the limitations of dependent claim 11, including an inner sleeve that encompasses the solvent bottle. Notably, the inner sleeve is a distinct and separate element from the sleeve of claim 10, as required by claim 11. Cherif-Cheikh fails to disclose any inner sleeve structure that encompasses the solvent bottle or is plugged into the solute bottle, as required by claim 11.

According to MPEP §2181, the Federal Circuit recognizes that the Examiner bears the initial burden of proof to demonstrate that the prior art reference either discloses or teaches the claimed invention. Applicant respectfully submits that in view of the above arguments, this burden has not been met. For the reasons presented above, Cherif-Cheikh fails to disclose all the elements required by independent claims 10 and 21 as well as dependent claim 11. Consequently, Cherif-Cheikh also fails to anticipate claims 10, 11 and 21 and any claims that depend therefrom.

**ii. 35 U.S.C. §103(a) Rejection - Cherif-Cheikh in view of Mohammad**

Claims 14-16 have been rejected, pursuant to 35 U.S.C. 103(a), as being obvious over Cherif-Cheikh in view of U.S. Patent No. 6,776,775 (hereinafter “Mohammad”). MPEP §2143 sets forth the three basic requirements that are necessary to support a prima facie case of obviousness for a §103 rejection:

**2143 Basic Requirements of a Prima Facie Case of Obviousness**

To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The proposed combination of Cherif-Cheikh in view of Mohammad that was applied in the Office Action fails to set forth all the limitations of dependent claim 14.

As shown in Figure 15, Mohammad discloses a hypodermic syringe needle assembly including a container wall 9 for housing a syringe plunger 18 and a syringe barrel 17 (See col. 12, lines 62-64). Syringe barrel 17 has a tip 19 that frictionally engages an interior surface of sleeve 3 to form a leak proof seal (See col. 12, line 65 - col. 13, lines 1-2). A radially projecting member 7 may be affixed to the outer surface of sleeve 3 (See col. 5, lines 61-62) and may be inserted within a longitudinal slot 10 located in container wall 9 (See col. 6, lines 12-13, 60-63).

Mohammad does not disclose any structure that corrects the aforementioned deficiencies of claims 10 and 21.

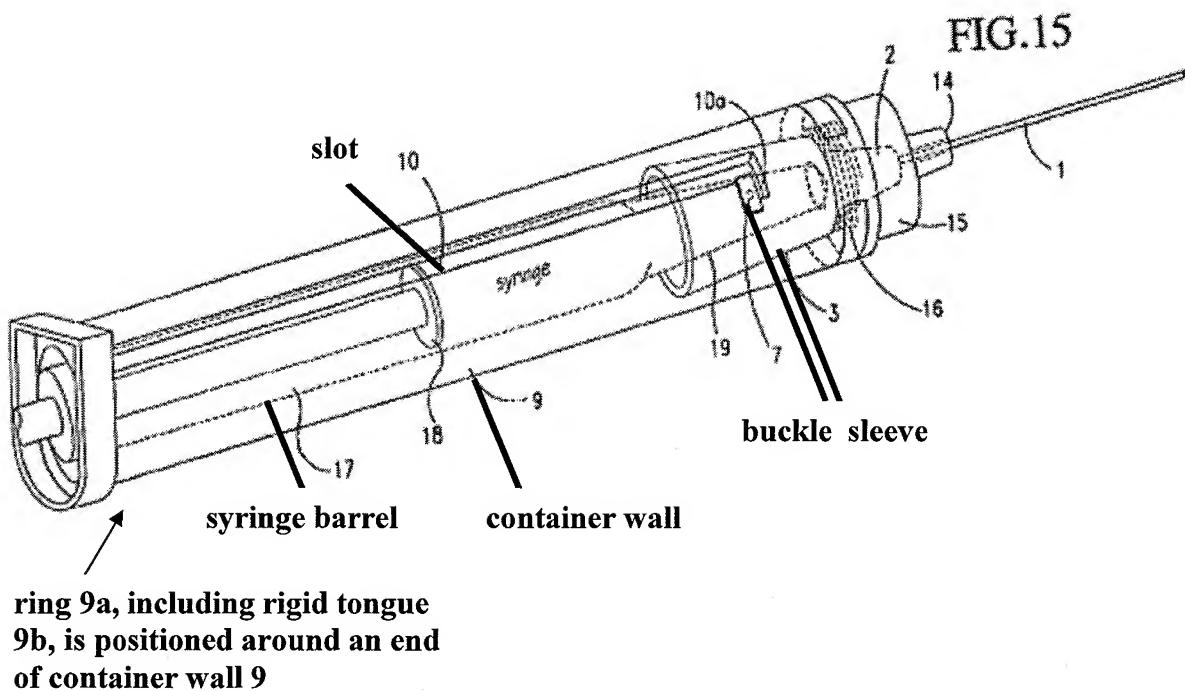
Furthermore, Cherif-Cheikh in view of Mohammad fails to disclose all the limitations of claim 14. Namely, the references fail to teach:

- (1) “plunger sleeve being provided with buckles ... two tongues are arranged on two sides of a lower edge of the plunger sleeve”;
- (2) “two tongues are arranged on two sides of a lower edge of the plunger sleeve so as to be symmetrical to the axis thereof”; and
- (3) “two slots corresponding to the positions of the tongues are arranged on the two sides of the upper edge of the inner sleeve so as to be symmetrical to the axis thereof.”

For purposes of clarification, the aforementioned limitations, i.e. plunger sleeve, buckles, two tongues and two slots and their position relative to the other claimed elements are structural limitations and not merely functional limitations of claim 14 as previously suggested by the Examiner.

Mohammad fails to disclose tongues arranged on a plunger sleeve or a plunger sleeve provided with buckles. Neither of these elements is positioned on the plunger sleeve, as required by claim 14. According to the Office Action, Mohammad discloses a rigid tongue 9b (i.e. tongues) and projecting members 7 (i.e. buckles) located on a syringe barrel 17 (i.e. plunger sleeve) that is integrated with the syringe plunger 18. However, as shown in Figures 10(a)-10(d), rigid tongue 9b, is attached to an edge of ring 9a and latches into a slot 10b positioned on container wall 9. Rigid tongue 9b is neither positioned on or attaches to any portion of the syringe barrel 17 (i.e. plunger sleeve). By contrast, as shown in Figure 15 below, container wall 9 and ring 9(a) that is described in the specification as being affixed to container wall 9 (See col. 6, lines 35-47; col. 11, lines 7-10; Fig. 4) surrounds and encompasses syringe barrel 17 (i.e. plunger sleeve). Mohammad therefore fails to disclose tongues arranged on two sides of a lower edge of the plunger sleeve, as required by claim 14. Furthermore, Mohammad also fails to disclose a plunger sleeve provided with buckles. Projecting members 7 (i.e. buckles) are affixed to affixed to the outer surface of sleeve 3 (See col. 5, lines 61-62), not syringe barrel 17 (i.e.

plunger sleeve). As shown in Fig. 15, projecting members 7 (i.e. buckles) are located on sleeve 3 which is a distinct and separate structure than syringe barrel 17 (i.e. plunger sleeve). According to the specification, tip 19 of syringe barrel 17 (i.e. plunger sleeve) is friction fitted into syringe barrel 17 (i.e. plunger sleeve) (See col. 12, line 65 - col. 13, lines 1-2). Neither the buckles nor tongues are located on syringe plunger 17, as required by claim 14.



Additionally, the Office Action cites rigid tongue 9b for meeting the two tongue limitation of claim 14. Mohammad, however, only discloses, teaches and suggests one rigid tongue 9b rather than two tongues. Furthermore, Mohammad fails to teach two tongues that are arranged so as to be symmetrical to the axis of the plunger sleeve, as required by claim 14.

Mohammad also fails to disclose two slots located on and symmetrical to an axis of an inner sleeve, wherein the two slots correspond to the two tongues. According to the claim 14, these slots must be located on an inner sleeve and must correspond to the position of the tongues. The Office Action refers to Figs. 14-15 for showing the requisite slots. Notably, the shown slots, 10a and 10 do not correspond to the location of rigid tongue 9b on ring 9a. According to the specification and Fig. 10(a), ring 9a is flush to slot 10b (See col. 6, lines 48-49). Mohammad, however only discloses one slot 10b rather than two slots corresponding to two rigid tongues 9b, as required by claim 14. Furthermore, slots 10a, 10b and 10 are all positioned on the exterior container wall 9 rather than on an inner sleeve, as required by claim 14 (See col. 12, lines 62-64). Slots 10a, 10b and 10 are also not positioned symmetrical to an axis of an inner sleeve.

Because Cherif-Cheikh in view of Mohammad fails to disclose all the limitations of claim 14, as discussed above, claim 14 and the claims which depend therefrom are not rendered obvious over Cherif-Cheikh in view of Mohammad.

### **iii. 35 U.S.C. §103(a) Rejection - Cherif-Cheikh in view of Mohammad and Peterson**

Claims 17-20 are rejected under 35 U.S.C. §103(a) as being rendered obvious by Cherif-Cheikh in view of Mohammad and U.S. Patent No. 5,520,639 (hereinafter “Peterson”). Notably, Peterson fails to correct the deficiencies of Cherif-Cheikh and Mohammad, as discussed above. Therefore, the combination of Cherif-Cheikh in view of Mohammad and Peterson does not render obvious independent claims 10, 21 or any claims that depend therefrom.

**3. Conclusion**

Applicant has made an earnest effort to place this application in condition for allowance. If Examiner Hayman feels that a telephone interview would expedite prosecution of this patent application, he is respectfully invited to telephone the undersigned at 215-599-0600. Contact with the undersigned via electronic mail at [gdoe@patentwise.com](mailto:gdoe@patentwise.com) is hereby authorized<sup>1</sup> per MPEP 502.03.

Respectfully submitted,

/Grace S. Doe/

Grace Doe  
Registration No. 59,257

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KNOBLE YOSHIDA & DUNLEAVY, LLC  
Eight Penn Center- Suite 1350  
1628 John F. Kennedy Boulevard  
Philadelphia, PA 19103  
(215) 599-0600 Main  
(215) 599-0601 Fax  
[gdoe@patentwise.com](mailto:gdoe@patentwise.com)

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<sup>1</sup> Recognizing that Internet communications are not secure, I hereby authorize the USPTO to communicate with me concerning any subject matter of this application by electronic mail. I understand that a copy of these communications will be made of record in the application file.